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**BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES**

Application Number: 10/786,725
Filing Date: February 25, 2004
Appellant(s): SWENSON ET AL.

Kirk M. Miles
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed February 1, 2010 appealing from the Office action mailed February 10, 2009.

(1) Real Party in Interest

A statement identifying by name the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The statement of the status of claims contained in the brief is correct.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is correct.

(6) Grounds of Rejection to be Reviewed on Appeal

The appellant's statement of the grounds of rejection to be reviewed on appeal is correct.

(7) Claims Appendix

A substantially correct copy of appealed claims 1-9 appears on page 22 of the Appendix to the appellant's brief. The minor errors are as follows: the listing lacks a statement that claims 10-38 are cancelled.

(8) Evidence Relied Upon

US 5,277,311	Hollister	01-1994
US 4,982,842	Hollister	01-1991
US 6,440,104	Newby et al.	08-2002
US 6,695,819	Kobayashi	02-2004
US 2003/0028152	Alesi et al.	02-2003
US 5,681,295	Gyure et al.	10-1997

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

1. **Claims 1-2, 5-6 & 9** are rejected under 35 U.S.C. 103(a) as obvious over Hollister (US 5,277,311) in view of Hollister (US 4,982,842).

In regards to **claims 1-2 & 9**, Hollister disclose(s) a holder assembly comprising:

a holder housing 2 for receiving a sample collection tube within a rearward end, a forward end of the holder housing 2 including;

a needle receiving port (6, 8) for receiving a needle cannula 28 therein and a safety shield 20 pivotably attached to a collar 18, said collar 18 having an opening therethrough for receiving a needle cannula 28 therethrough, the safety shield 20 is capable of being pivoted over at least a portion of a needle 12 received within the needle receiving port (6, 8) of the holder housing 2,

wherein the safety shield 20 and the collar 18 are axially rotatable with respect to the holder housing 2 about an axis of the holder housing 2, such that the safety shield 20 and the collar 18 can be radially rotated to a desired position around a needle 28 received within the

needle receiving port (6, 8) and around the axis of the holder housing 2 without axial movement of the collar along the axis (see figs. 1-5; col. 3, lines 23-41);

wherein the collar 18 is annular (see figs. 1-5);

wherein the shield 20 and the collar 18 are integral and attached through a living hinge 24 (see figs. 1-5);

wherein the shield 20 comprises a rearward end, a forward end, and a longitudinal opening in the forward end for receiving a needle (see fig. 4);

wherein the collar 18 attaches to the holder housing 2 via a protrusion 16 and groove 22 means (see figs.4-5);

wherein the protrusion 16 and groove 22 are annular (see figs. 4-5);

wherein the collar 18 is rotatable about an axis of the holder housing 2 (see col. 3, lines 23-41);

wherein the collar 18 further comprises an interior opening for receiving a needle cannula 28 therein (see figs. 1-4);

wherein the interior opening includes structure 14 for engagement with corresponding mating structure on a needle cannula assembly (see fig.3).

Hollister ('311) discloses a holder assembly, as described above, that fails to explicitly teach an annular skirt.

However, **Hollister ('842)** discloses a holder assembly comprising an annular skirt extending about a receiving port (see fig. 4; col. 4, lines 26-31; col. 6, lines 67-68; col. 7, lines 1-3).

In regards to **claim 1**, since Hollister ('842) teaches a holder assembly wherein addition of an annular skirt 76 allows an annular protrusion 18 on a collar 2 to externally mate with a holder housing 72 (see fig. 4; col. 4, lines 26-31; col. 6, lines 67-68; col. 7, lines 1-3), it would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to provide the holder assembly of Hollister ('311) with an annular skirt such that the collar is received between the annular skirt and the receiving port of the holder housing as taught by Hollister ('842) in order to allow an annular protrusion on the collar to externally mate with a holder housing.

In regards to **claims 1 & 5-6**, since Hollister ('311) teaches a holder assembly comprising an annular protrusion 16 and a groove 22 for rotatably (i.e. by torque) and frictionally mating the collar 18 against the holder housing 2 such that the safety shield 20 and the collar 18 are axially rotatable with respect to the holder housing 20 about an axis of the holder housing 2 without axial movement of the collar along the axis in order to permit the phlebotomist or nurse to torquably rotate the collar and shield to view the true angle or position of the bevel of the cannula so that the cannula can be more easily and accurately inserted into, for example, the vein of a patient (see col. 1, lines 45-68; col. 2, lines 1-11; col. 3, lines 23-41), it would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to provide the holder assembly of Hollister ('311) as modified by Hollister ('842) above with a collar that includes a protrusion or groove for respectively mating with a groove or protrusion on the holder housing as claimed in order to rotatably (i.e. by torque) and frictionally hold the collar against the holder housing such that a phlebotomist or nurse can torquably rotate the collar and shield to

view the true angle or position of the bevel of the cannula so that the cannula can be more easily and accurately inserted into, for example, the vein of a patient.

2. **Claims 3-4** are rejected under 35 U.S.C. 103(a) as obvious over Hollister ('311) in view of Hollister ('842), and further in view of Kobayashi (US 6,695,819).

Hollister ('311) as modified by Hollister ('842) discloses a holder assembly, as described above in claim 1, that fails to explicitly teach a pivot assembly wherein a hanger bar is part of the safety shield and the hook arm is part of collar.

However, **Kobayashi** discloses a holder assembly comprising a hanger bar 78 attached to a safety shield 70 and a hook arm 36 attached to a collar 30 such that the safety shield 70 pivots about the collar 30 (see figs. 2, 4, 8-9 & 12).

Since providing a holder assembly with a pin hinge or a living hinge is an art recognized substitution (see fig. 2A & col. 8, lines 25-35 of US 6,592,556), it would have been obvious to one ordinary skill in the art at the time Applicant's invention was made to provide the holder assembly of Hollister ('311) as modified by Hollister ('842) above with a pivot assembly comprising a hanger bar attached to a safety shield and a hook arm attached a collar as taught by Kobayashi in order to attach the safety shield to the collar such that the safety shield can pivot with respect to the collar for selectively covering a needle cannula.

3. **Claims 3-4** are rejected under 35 U.S.C. 103(a) as obvious over Hollister ('311) in view of Hollister ('842), and further in view of Newby et al. (US 6,440,104).

Hollister ('311) as modified by Hollister ('842) discloses a holder assembly, as described above in claim 1, that fails to explicitly teach a pivot assembly wherein a hanger bar is part of the safety shield and the hook arm is part of collar.

However, Newby et al. disclose a holder assembly comprising a hanger bar 182 attached to a safety shield 140 and a hook arm 114 attached to a collar 90 such that the safety shield 140 pivots about the collar 90 (see figs. 1-4).

Since providing a holder assembly with a pin hinge or a living hinge is an art recognized substitution (see fig. 2A & col. 8, lines 25-35 of US 6,592,556), it would have been obvious to one ordinary skill in the art at the time Applicant's invention was made to provide the holder assembly of Hollister ('311) as modified by Hollister ('842) above with a pivot assembly comprising a hanger bar attached to a safety shield and a hook arm attached a collar as taught by Newby et al. in order to attach the safety shield to the collar such that the safety shield can pivot with respect to the collar for selectively covering a needle cannula.

4. **Claim 7** is rejected under 35 U.S.C. 103(a) as obvious over Hollister ('311) in view of Hollister ('842), Newby et al. ('104), and further in view of Alesi et al. (US 2003/0028152).

Hollister ('311) as modified by Hollister ('842) and Newby et al. discloses a holder assembly, as described above in claim 4, that fails to teach a holder assembly wherein the annular skirt on the holder housing substantially encloses an open end of the hook arm.

However, Newby et al. teach that it is known to provide holder assemblies with a hinge comprising a hook arm attached to a collar (see figs. 1-4) and Alesi et al. teach that it is known to provide a living hinge attached to the annular skirt 8 of the holder housing 2 (see abstract; see figs. 7-8; see par 0033); since it known to substitute living hinges with hinges comprising holes and pegs that securely latch onto the holes for attachment and rotation therethrough as described above, it would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to provide the holder assembly of Hollister ('311) as modified by Hollister

(‘842) and Newby et al. above with an annular skirt that encloses an open end of the hook arm as claimed in order to achieve a holder assembly wherein, the shield, while only detachably attachable to the collar, also enjoys the characteristics of a full hinge, notably a secure attachment to the housing and collar (i.e. similar to that of the latching of the full hinge).

5. **Claim 7** is rejected under 35 U.S.C. 103(a) as obvious over Hollister (‘311) in view of Hollister (‘842), Kobayashi (‘819), and further in view of Alesi et al. (US 2003/0028152).

Hollister (‘311) as modified by Hollister (‘842) and Kobayashi discloses a holder assembly, as described above in claim 4, that fails to teach a holder assembly wherein the annular skirt on the holder housing substantially encloses an open end of the hook arm.

However, Kobayashi teaches that it is known to provide holder assemblies with a hinge comprising a hook arm attached to a collar (see figs. 2, 4, 8-9 & 12) and Alesi et al. teach that it is known to provide a living hinge attached to the annular skirt 8 of the holder housing 2 (see abstract; see figs. 7-8; see par 0033); since it known to substitute living hinges with hinges comprising holes and pegs that securely latch onto the holes for attachment and rotation therethrough as described above, it would have been obvious to one of ordinary skill in the art at the time Applicant’s invention was made to provide the holder assembly of Hollister (‘311) as modified by Hollister (‘842) and Kobayashi above with an annular skirt that encloses an open end of the hook arm as claimed in order to achieve a holder assembly wherein, the shield, while only detachably attachable to the collar, also enjoys the characteristics of a full hinge, notably a secure attachment to the housing and collar (i.e. similar to that of the latching of the full hinge).

6. **Claim 8** is rejected under 35 U.S.C. 103(a) as being unpatentable over Hollister (‘311) in view of Hollister (‘842), and further in view of Gyure et al. (US 5,681,295).

Hollister ('311) as modified by Hollister ('842) teaches a holder assembly, as described above, that fails to explicitly teach a collar having one or more slits in a rearward portion thereof.

However, **Gyure et al.** disclose a holder assembly comprising a collar having one or more slits in a rearward portion thereof (see figs. 3-4; col. 3, lines 50-67; col. 4, lines 1-27).

Since Gyure et al. teach a holder assembly comprising a collar having one or more slits in a rearward portion thereof so as to provide the collar with some flexibility to allow it to be easily snapped into place (see Gyure et al., col. 4, lines 20-27), it would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to provide the holder assembly of Hollister ('311) as modified by Hollister ('842) with one or more slits as taught by Gyure et al. in order to provide the collar with some flexibility to allow it to be easily snapped into place.

(10) Response to Argument

The Appellants argue that:

(A) claims 1,2 and 9 are not rendered obvious under 35 U.S.C. 103(a) by US 5,277,311 to Hollister ("Hollister ('311)" hereinafter) in view of US 4,982,842 to Hollister ("Hollister ('842)" hereinafter);

(B) claims 5-6 are not rendered obvious under 35 U.S.C. 103(a) by Hollister ('311) in view of Hollister ('842);

(C) claims 3-4 are not rendered obvious under 35 U.S.C 103(a) by Hollister ('311) in view of Hollister ('842) and further in view of US 6,695,819 to Kobayashi ("Kobayashi" hereinafter);

(D) claims 3-4 are not rendered obvious under 35 U.S.C 103(a) by Hollister ('311) in view of Hollister ('842) and further in view of US 6,440,104 to Newby et al. ("Newby" hereinafter);

(E) claim 7 is not rendered obvious under 35 U.S.C 103(a) by Hollister ('311) in view of Hollister ('842), Newby and further in view of US 2003/0028152 to Alesi et al. ("Alesi" hereinafter);

(F) claim 7 is not rendered obvious under 35 U.S.C 103(a) by Hollister ('311) in view of Hollister ('842), Kobayashi and further in view of Alesi;

(G) claim 8 is not rendered obvious under 35 U.S.C 103(a) by Hollister ('311) in view of Hollister ('842) and further in view of US 5,681,295 to Gyure et al. ("Gyure" hereinafter).

These arguments have been considered by the Examiner but have not deemed persuasive for the following reasons:

(A) In response to the Appellants' argument that claims 1,2 and 9 are not rendered obvious under 35 U.S.C. 103(a) by Hollister ('311) in view of Hollister ('842) because the combination allegedly fails to provide any suggestion or motivation to provide:

- (i) an annular skirt (***as per claims 1-2 & 9 only***),
- (ii) locate a mounting collar between an annular skirt and a needle receiving portion of the holder housing (***as per claims 1-2 & 9 only***), and
- (iii) redesign the relationship between the mounting collar and the holder housing to form an interfitting relationship of the collar with the annular skirt such that

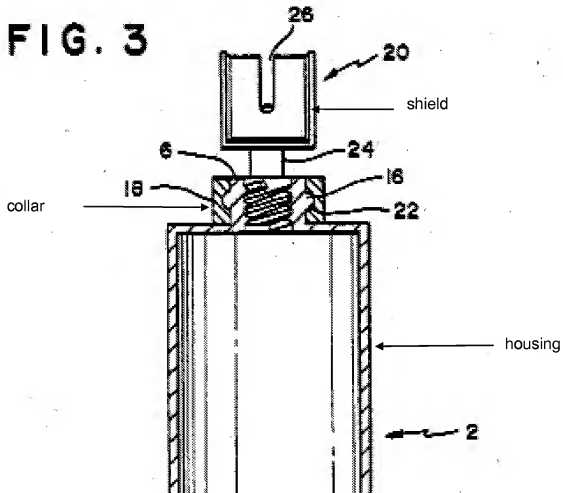
the shield can pivot with respect to the collar and the annular skirt (*as per claims 5-6 only*). With regard to the Appellants' argument, the Examiner respectfully traverses.

In response to Appellants' argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, *there is some teaching, suggestion, or motivation to do so found in the cited references since Hollister ('842) teaches that it is known to use an annular skirt 76 to attach a collar 2 to a housing 74 (see fig. 4).*

For example, Hollister ('311) teaches a fluid container housing 2 having a distal end 6, which serves as a needle receiving port for receiving a needle cannula 28 therein; wherein the housing 2 is adapted to receive a sample collection tube 46 (see fig. 1); Hollister ('311) further teaches that the container housing 2 includes a safety shield 20 pivotally attached to an annular collar 18 via flexible hinge 24 (see fig. 2); the annular collar 18 attaches to the housing 2 via a boss or protrusion 16 on the distal end 6 of the housing 2 and an internal circumferential groove 22 on the annular collar 18 (see fig. 4); the safety shield 20 and the collar 18 are axially rotatable with respect to the housing 2 about an axis of the housing 2 without axial movement of the collar 18 along the axis in order to permit the phlebotomist or nurse to torquably rotate the collar 18 and

Art Unit: 3736

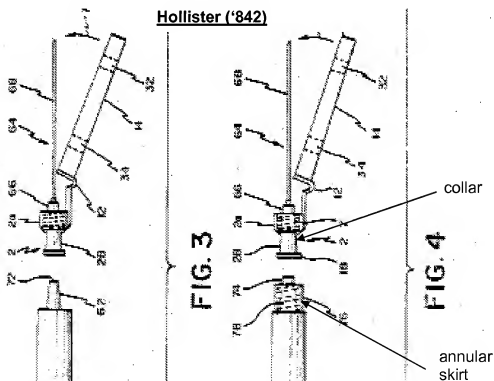
shield 20 to view the true angle or position of the bevel of the cannula 28 so that the cannula 28 can be more easily and accurately inserted into, for example, the vein of a patient (see col. 1, lines 45-68; col. 2, lines 1-11; col. 3, lines 23-41).



As such, Hollister ('311) meets each and every limitations from claims 1-2 & 9 except for (i) an annular skirt, and, (ii) a mounting collar located between an annular skirt and a needle receiving portion of the holder housing. For example, claims 1-2 & 9 do not require a "redesign" of "the relationship between the mounting collar and the

holder housing to form an interfitting relationship of the collar with the annular skirt such that the shield can pivot with respect to the collar and the annular skirt.” Instead, only claims 5-6 are pertinent to the alleged “redesign” of “the relationship between the mounting collar and the holder housing to form an interfitting relationship of the collar with the annular skirt such that the shield can pivot with respect to the collar and the annular skirt.”

On the other hand, Hollister ('842) teaches that it is known to mate a collar 6, having a base 2 and a section 2B, to a housing 60 without an annular skirt via a “male luer” or housing end 62 (see fig. 3) or alternately to attach the collar 6 to a housing 72 with the addition of an annular skirt 76 via a “male luer” or housing end 74 (see fig. 4).



Hollister ('842) also teaches that when adding an annular skirt 76, a securing means, in this case in the form of threads 78 on the annular skirt 76 and a protrusion 18 on the collar 6, may be added to secure the collar 6 to the housing 72 even though the mating means (in this case a slip-fit) of the housing end 74 to the collar 6, remains the same and unchanged (i.e. slip-fittedly mated) (see col. 6, lines 67-68; col. 7, lines 1-5).

In other words, while Hollister ('311) teaches one way to attach a collar 18 to a housing 2 and housing end 6 (i.e. without an annular skirt) (see figs. 1-3); Hollister ('842) teaches that one of ordinary skill in the art can alternately mate a collar 6 to a housing 72 or housing end 74 with or without the addition of an annular skirt 76 (see figs. 3-4). When using an annular skirt 76 as shown in figure 4 of Hollister ('842), the mating means (i.e. in this case a slip-fit) between the collar 6 and the housing end 74 is maintained and unchanged (see col. 6, lines 67-68; col. 7, lines 1-5) while a securing means (i.e. in this case threads 78 on the annular skirt 76 and an extension on collar 6) between the collar 6 and annular skirt 76 is added to mate the collar 6 to the housing 72 via the annular skirt 76 (see fig. 4). As a result, the collar 6 of fig. 4 is attached to the housing 72 at two locations instead of one as in fig. 3 resulting in a more secure connection between the collar and the housing.

As such, applying the teachings of Hollister ('842) to those of Hollister ('311) to *alternately* add an annular skirt to the housing 2 of Hollister ('311) would necessarily involve the maintenance of the mating means (boss/groove assembly) between the collar 18 and the housing end 6 of Hollister ('311), and the addition of a securing means between the collar 18 and the presumably added annular skirt to mate the collar 18 to

the annular skirt, and ultimately to the housing 2 as taught by Hollister ('842) and as explained above. As such, since Hollister ('311) promotes the benefits of having a housing assembly comprising an annular protrusion 16 and a groove 22 for rotatably (i.e. by torque) and frictionally mating the collar 18 against the housing 2 such that the safety shield 20 and the collar 18 are axially rotatable with respect to the housing 20 about an axis of the housing 2 without axial movement of the collar along the axis in order to permit the phlebotomist or nurse to torquably rotate the collar and shield to view the true angle or position of the bevel of the cannula so that the cannula can be more easily and accurately inserted into, for example, the vein of a patient (see col. 1, lines 45-68; col. 2, lines 1-11; col. 3, lines 23-41); the Examiner thus submits that, contrary to the Appellants' contention that there's no suggestion or motivation to "redesign the relationship between the mounting collar and the holder housing to form an interfitting relationship of the collar with the annular skirt such that the shield can pivot with respect to the collar and the annular skirt," it would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to provide the housing assembly of Hollister ('311) with an annular skirt such that the collar is received between the annular skirt and the receiving port of the housing as taught by Hollister ('842) in a rotatable fashion via an annular protrusion/groove assembly as taught by Hollister ('311) in order to rotatably (i.e. by torque) and frictionally hold the collar against the housing such that a phlebotomist or nurse can torquably rotate the collar and shield to view the true angle or position of the bevel of the cannula so that the cannula can be more easily and accurately inserted into, for example, the vein of a patient (see pages 3-4 of the last

Office action dated February 10, 2009). In other words, the Examiner finds it obvious that one of ordinary skill in the art, armed with both Hollister ('311) and Hollister ('842), would necessarily improve the securing means between the collar 18 of Hollister ('311) and a presumably added annular skirt as suggested by Hollister ('842) to include a groove/boss mechanism as taught by Hollister ('311) in order to keep the trumpeted improvement offered by the rotatable characteristics of the device of Hollister ('311), which allows a phlebotomist or nurse to torquably rotate the collar and shield to view the true angle or position of the bevel of the cannula so that the cannula can be more easily and accurately inserted into, for example, the vein of a patient. In fact, doing otherwise (i.e. using a securing means that does not allow a rotatable connection) may go against the principle of operation of Hollister ('311); for example, Hollister ('311) touts the groove and boss mechanism of its device as an improvement over the prior art, which uses threaded mechanisms that may end up in any orientation and would thus prevent the phlebotomist from viewing the true angle of the cannula (see col. 1, lines 45-68; col. 2, lines 1-11). As such, one of ordinary skill in the art attempting to improve the device Hollister ('311) to include an annular skirt as taught by Hollister ('842) would find it obvious to keep the rotatable connection mechanism of Hollister ('311), which Hollister ('311) extols as being able to allow a phlebotomist or nurse to torquably rotate the collar and shield to view the true angle or position of the bevel of the cannula so that the cannula can be more easily and accurately inserted into, for example, the vein of a patient.

Moreover, since

a) one of ordinary skill in the art could have combined the teachings of Hollister ('311) with those of Hollister ('842) as suggested in the rejections supra by known methods,

b) in the combination, each element (i.e. among others, the housing and housing end of Hollister ('311) and the annular skirt of Hollister ('842)) in the combination would have performed the same function as it did separately (i.e. the housing of Hollister ('311) would serve the same purpose of receiving a sample collection tube within a rearward end, the housing end of Hollister ('311) would serve the same purpose of mating a collar to the housing, and the annular skirt of Hollister ('842) would serve the same purpose of securing the collar to the housing, the boss/groove mechanism of Hollister ('311) would serve the same purpose of allowing a phlebotomist or nurse to torquably rotate the collar and shield to view the true angle or position of the bevel of the cannula so that the cannula can be more easily and accurately inserted into, for example, the vein of a patient); and,

c) one of ordinary skill in the art would have recognized that the results of the combination were predictable,

The Examiner submits that combining prior art elements according known methods to yield predictable results has recently been held to be obvious (see *KSR International Co. v. Teleflex Inc.*, 550 U.S.--, 82 USPQ2d 1385 (2007)).

The Appellants further contend that Hollister ('842) teaches a skirt that is to be used for an entirely different purpose, namely, to lock the needle to the syringe device. However, the Examiner submits that the "skirt" of Hollister ('842) refers, in fact, to an annular collar 6 having a base 2, a section 2b and a hub 16 as better illustrated in figure

1A (see also col. 4, lines 24-37); the annular collar 6 of Hollister ('842) even includes a safety shield 14 pivotably attached thereto such that the safety shield 14 is capable of being pivoted over at least a portion of a needle via living hinge 12 as shown in figs. 1A, 3 & 4 (see col. 4, lines 38-44). As such, similar to Hollister ('311), the "skirt" or annular collar 6 of Hollister ('842) is used to attach a safety shield 14 to the housing (60, 72), which safety shield 14 prevents a person from being accidentally pricked by the needle, after the needle has been used and is to be disposed of (see col. 6, lines 24-28 of Hollister ('842)). For example, there is no other reason to have the collar 6 or "skirt" on the device of Hollister ('842) other than to include a safety shield 14 in the device. For instance, the needle 68, depicted in figs. 3-4 of Hollister ('842), could have simply been attached directly to the housing itself. As such, contrary to the Appellants' argument, the Examiner submits that the main role of the "skirt" or collar 6 is to attach a safety shield to the housing, which safety shield prevents a person from being accidentally pricked by the needle, after the needle has been used and is to be disposed of.

The Appellants also contend that Hollister ('842) fail to provide any suggestion to modify the threads to include a boss and groove mechanism to allow for rotation of a shield/collar assembly; however, the Examiner finds the suggestion in Hollister ('311), which is an improvement that would allow a phlebotomist or nurse to torquably rotate the collar and shield to view the true angle or position of the bevel of the cannula so that the cannula can be more easily and accurately inserted into, for example, the vein of a patient, as explained above.

The Appellants additionally argue that Hollister ('842) teaches away from any type of radial rotation during use due to the possibility of leakage occurring between the luer interface of male luer (74) and section (2b), thus rendering the device inoperable. However the Appellants have failed to provide any evidence of this assertion.

MPEP 2141.02 (VI) reads as follows

A prior art reference must be considered in its entirety, i.e., as a whole, including portions that would lead away from the claimed invention. *W.L. Gore & Associates, Inc. v. Garlock, Inc.*, 721 F.2d 1540, 220 USPQ 303 (Fed. Cir. 1983), cert. denied, 469 U.S. 851 (1984) (Claims were directed to a process of producing a porous article by expanding shaped, unsintered, highly crystalline poly(tetrafluoroethylene) (PTFE) by stretching said PTFE at a 10% per second rate to more than five times the original length. The prior art teachings with regard to unsintered PTFE indicated the material does not respond to conventional plastics processing, and the material should be stretched slowly. A reference teaching rapid stretching of conventional plastic polypropylene with reduced crystallinity combined with a reference teaching stretching unsintered PTFE would not suggest rapid stretching of highly crystalline PTFE, in light of the disclosures in the art that teach away from the invention, i.e., that the conventional polypropylene should have reduced crystallinity before stretching, and that PTFE should be stretched slowly.). However, "the prior art's mere disclosure of more than one alternative does not constitute a teaching away from any of these alternatives because such disclosure does not criticize, discredit, or otherwise discourage the solution claimed...." *In re Fulton*, 391 F.3d 1195, 1201, 73 USPQ2d 1141, 1146 (Fed. Cir. 2004). >See also MPEP § 2123.

In the above case law, the prior art teachings with regard to unsintered PTFE indicated the material does not respond to conventional plastics processing, and the material should be stretched slowly. A reference teaching rapid stretching of conventional plastic polypropylene with reduced crystallinity combined with a reference teaching stretching unsintered PTFE would not suggest rapid stretching of highly crystalline PTFE, in light of the disclosures in the art that teach away from the invention, i.e., that the conventional polypropylene should have reduced crystallinity before stretching, and that PTFE should be stretched slowly.). As such, the Examiner finds no correlation in the instant case that would lead the Appellants to claim that the instant

situation is indeed a teaching away. For example, the prior art of Hollister ('842) "does not criticize, discredit or otherwise discourage" the use of a groove and boss mechanism for radial rotation.

Moreover, with regard to the Appellants' assertion that the combination would be inoperable, MPEP, section 2145 (I) clearly stipulates:

The arguments of counsel cannot take the place of evidence in the record. In re Schulze, 346 F.2d 600, 602, 145 USPQ 716, 718 (CCPA 1965); In re Geisler, 116 F.3d 1465, 43 USPQ2d 1362 (Fed. Cir. 1997) ("An assertion of what seems to follow from common experience is just attorney argument and not the kind of factual evidence that is required to rebut a prima facie case of obviousness.").

As such, the Appellants argument that any type of radial rotation during use would possibly lead to leakage occurring between the luer interface of male luer (74) and section (2b), thus rendering the device inoperable is unsubstantiated in the absence of a timely-provided valid affidavit and/or declaration.

(B) Appellants argue that claims 5-6 are not rendered obvious under 35 U.S.C. 103(a) by Hollister ('311) in view of Hollister ('842). In response thereof, the Examiner respectfully traverses. For example, the Office action states that it would have been obvious to include a groove and boss mechanism between the collar 18 of Hollister ('311) and a presumably added annular skirt as taught by Hollister ('842) in order to allow a phlebotomist or nurse to torquably rotate the collar and shield to view the true angle or position of the bevel of the cannula so that the cannula can be more easily and accurately inserted into, for example, the vein of a patient (see page 4 of the last Office action). As such, the modification proposed in the office action would result in a collar having an external groove and a presumably added annular skirt as taught by

Hollister ('842) having a boss/groove assembly as taught by Hollister ('311) in order to allow a phlebotomist or nurse to torquably rotate the collar and shield to view the true angle or position of the bevel of the cannula so that the cannula can be more easily and accurately inserted into, for example, the vein of a patient. The Examiner's reasons for finding the combination obvious are fully explained above in section (A).

(C) Appellants argue that claims 3-4 are not rendered obvious under 35 U.S.C 103(a) by Hollister ('311) in view of Hollister ('842) and further in view of US 6,695,819 to Kobayashi ("Kobayashi" hereinafter). In response thereof, the Examiner respectfully traverses. However, the Appellants have not provided separate arguments for claims 3-4 in this section.

(D) Appellants argue that claims 3-4 are not rendered obvious under 35 U.S.C 103(a) by Hollister ('311) in view of Hollister ('842) and further in view of US 6,440,104 to Newby et al. ("Newby" hereinafter). In response thereof, the Examiner respectfully traverses. However, the Appellants have not provided separate arguments for claims 3-4 in this section.

(E) Appellants argue that claim 7 is not rendered obvious under 35 U.S.C 103(a) by Hollister ('311) in view of Hollister ('842), Newby and further in view of US 2003/0028152 to Alesi et al. ("Alesi" hereinafter). In response thereof, the Examiner respectfully traverses. The claim only pertains to arrangement in which an annular skirt on the housing would substantially enclose an open end of a hook arm. The Appellants do not dispute the fact that Newby does teach a hinge having a hook arm as claimed. The Appellants further do not dispute that it is known to use a full hinge having holes

and pegs to securely attach a housing to a collar. Since Alesi teaches that it is known to attach a living hinge directly onto annular skirt, the Examiner submits it would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to provide the holder assembly of Hollister ('311) as modified by Hollister ('842) and Newby et al. above with an annular skirt that encloses an open end of the hook arm as claimed in order to achieve a holder assembly wherein, the shield, while only detachably attachable to the collar, also enjoys the characteristics of a full hinge, notably a secure attachment to the housing and collar (i.e. similar to that of the latching of the full hinge). For example, the hook-arm hinge of the collar of Hollister ('311) as modified by ('842) and Newby et al. above would be substantially encircled (covered) by the presumably added annular skirt to form a full hinge that it is known to securely attach a housing to a collar.

(F) Appellants argue that claim 7 is not rendered obvious under 35 U.S.C 103(a) by Hollister ('311) in view of Hollister ('842), Kobayashi and further in view of Alesi. In response thereof, the Examiner respectfully traverses. The claim pertains to arrangement in which an annular skirt on the housing would substantially enclose an open end of a hook arm. The Appellants do not dispute the fact that Kobayashi does teach a hinge having a hook arm as claimed. The Appellants further do not dispute that it is known to use a full hinge having holes and pegs to securely attach a housing to a collar. Since Alesi teaches that it is known to attach a living hinge directly onto annular skirt, the Examiner submits it would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to provide the holder assembly of Hollister

('311) as modified by Hollister ('842) and Kobayashi above with an annular skirt that encloses an open end of the hook arm as claimed in order to achieve a holder assembly wherein, the shield, while only detachably attachable to the collar, also enjoys the characteristics of a full hinge, notably a secure attachment to the housing and collar (i.e. similar to that of the latching of the full hinge). For example, the hook-arm hinge of the collar of Hollister ('311) as modified by ('842) and Kobayashi above would be substantially encircled (covered) by the presumably added annular skirt to form a full hinge that it is known to securely attach a housing to a collar.

(G) Appellants argue that claim 8 is not rendered obvious under 35 U.S.C 103(a) by Hollister ('311) in view of Hollister ('842) and further in view of US 5,681,295 to Gyure et al. ("Gyure" hereinafter). In response thereof, the Examiner respectfully traverses. Appellants argue that Gyure fails to teach slits as claimed. However, in fig. 3, Gyure does disclose a series of slits 43 forming a stepped configuration that "also gives the collar some flexibility to allow it to easily be snapped into place during the assembly process" (see col. 4, lines 20-27). As such, the Examiner submits that it would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to provide the holder assembly of Hollister ('311) as modified by Hollister ('842) with one or more slits as taught by Gyure et al. in order to provide the collar with some flexibility to allow it to be easily snapped into place.

(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

/Rene Towa/

Examiner, Art Unit 3736

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Max Hindenburg

/Max Hindenburg/

Supervisory Patent Examiner, Art Unit 3736

Melanie Kemper

/Melanie Kemper/

Reviewer, TC 3700